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10/575,875	02/01/2007	Patrick Lewis Blott	SMNPH.004APC	6850

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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06/17/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/575,875	Applicant(s) BLOTT ET AL.	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 9, 21 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-20, 22 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-8, 11-14, 16-19 and 22 are amended.
2. Claims 9, 21 and 23 are canceled.
3. Claims 24-29 are new.
4. Claims 1-8, 10-20, 22 and 24-29 are examined on the merits.

Response to Amendment

5. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

6. Applicant's arguments, see Remarks, pages 9-12, filed 05/26/2009, with respect to the rejection(s) of claim(s) 1, 14 and 19 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of US 5,055,198.

7. Applicant's arguments with respect to limitations "bleeding valve" and bleeding mechanism" have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's arguments filed 05/26/2009 have been fully considered but they are not persuasive:

9. With respect to claims 1, 14 and 19, Applicants argue that Swanbeck does not disclose the claimed invention because the reference does not disclose, suggest or appreciate heating the fluid before the fluid enters the cover to maintain the wound.

However, Swanbeck expressly discloses the bottle 15 with the treatment solution placed in a thermostatically regulated water bath (page 4, lines 3-5). Since the bottle 15 with the

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treatment solution has been positioned before the wound dressing 10 (See Fig. 1) the fluid necessarily has been warmed before it enters the cover.

10. Applicants further argue that the rejection based on *The Columbia Electronic Encyclopedia* is improper because *The Columbia Electronic Encyclopedia* is nonanalogous art.

However, Examiner did not make any rejection based on *The Columbia Electronic Encyclopedia*, but only based on the Common Knowledge in the Art, as it has been expressly stated in the Office Action, wherein *The Columbia Electronic Encyclopedia* has been brought not as a ground of rejection but as an evidence of Common Knowledge in the Art: It would have been obvious to one having ordinary skill in the art at the time the invention was made to maintain the temperature of the wound treatment fluids between 34 and 40 degrees Celsius, since it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is from 34 to 42 degrees Celcius (See *The Columbia Electronic Encyclopedia*), which encompasses the claimed range (**MPEP 2144.03 (A-E)**).

11. Applicants further argue that refer to *The Columbia Electronic Encyclopedia* is improper because *The Columbia Electronic Encyclopedia* makes no mention of the effect of body temperature on wound healing.

However, the healing process temperature range is necessarily encompassed by the normal temperature range of the body, since it was known in the art that exceeding the superior limit of the normal body temperature range brings the risk to meet the protein coagulation phenomena.

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Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

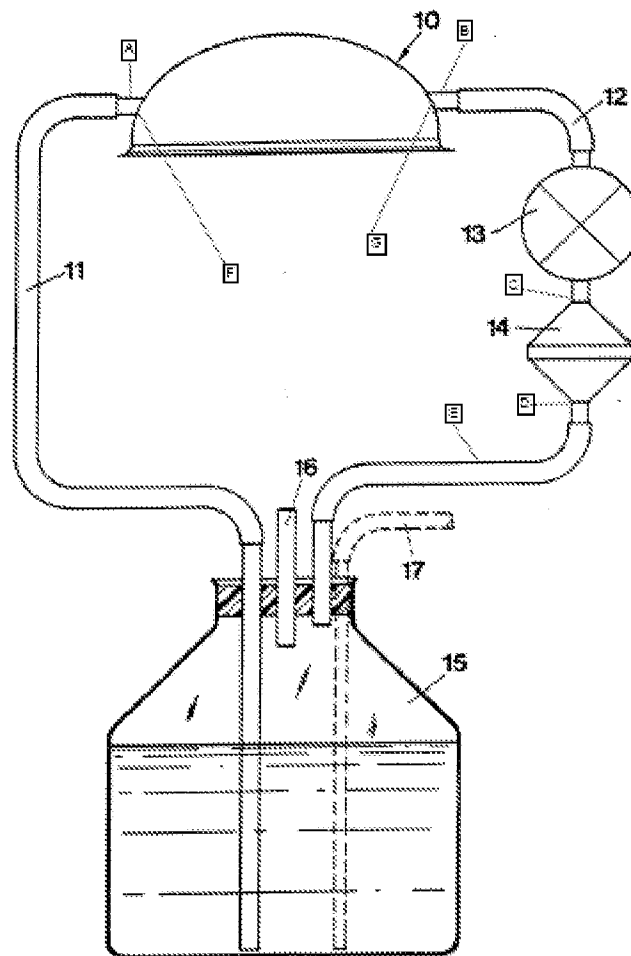
15. Claims 1-5, 10-20, 22 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck (WO 84/01904) in view of Shettigar (US 5,055,198).

16. In Re claim 1, Swanbeck discloses a device for rinsing and treating wounds comprising:

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a suction cup 10 (Fig. 1) which is the wound dressing made of rubber or plastic (p. 2, ln. 33) and consequently fully capable of forming a fluid-tight seal or closure over a wound; the feed and discharge tubes (inlet and outlet pipes) A and B (Fig. 1) connected to outlet and discharge tubes 11 and 12 (p. 2, ln. 34, 35; Fig. 1); a sterilizing filter (fluid cleansing means) 14 (p. 3, ln. 33; Fig. 1) having an inlet port C (Fig. 1) connected to a fluid offtake tube 12 (Fig. 1) and an outlet port D (Fig. 1) connected to a fluid recirculation tube E (Fig. 1); a fluid reservoir 15 (Fig. 1); a peristaltic pump 13 (p. 2, ln. 37 – p. 4, ln. 1; Fig. 1) which is a device for moving fluid through the wound dressing and cleansing means; an apparatus for supplying thermal energy (p. 4, ln. 3-5).

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FIG 1

Swanbeck does not expressly disclose the apparatus comprising a means for bleeding the fluid flow path to bleed fluid from the recirculation tube.

Shettigar teaches the blood recovery system comprising valve 62 (Fig. 1) that is a means for leading part of the liquid from the recirculation tube A (Fig. 1) to the external container 48 (Col. 11, lines 34-35; Col. 30, lines 61-62; Fig. 1).

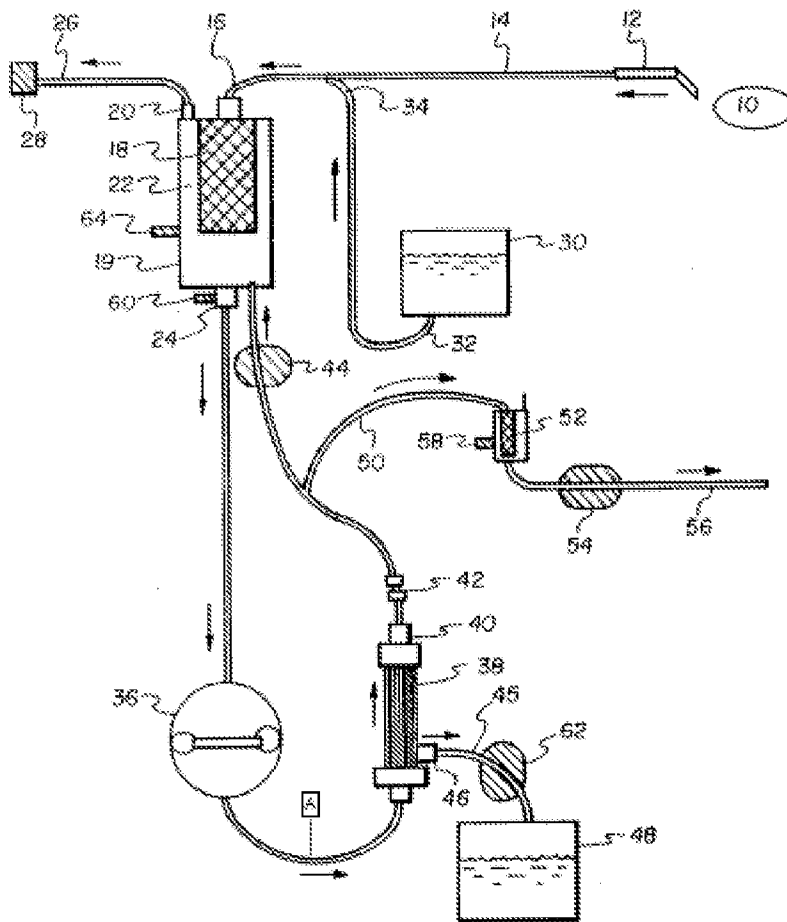


Fig. 10

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the recirculation line of Swanbeck with the bleeding valve, as taught by Shettigar in order to lead part of the liquid to the external container if desired (Shettigar, Col. 30, lines 61-62).

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a).

Ex Parte Smith, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct.

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1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

Swanbeck in view of Shettigar do not expressly disclose the apparatus maintaining the temperature on the wound in the range between 34 and 40 degree Celsius to optimize the metabolic activities of physiologically active components within the wound dressing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to maintain the temperature of the wound treatment fluids between 34 and 40 degrees Celsius, since it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is from 34 to 42 degrees Celcius (See *The Columbia Electronic Encyclopedia*), which encompasses the claimed range (**MPEP 2144.03 (A-E)**).

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17. In Re claim 2, Swanbeck discloses the apparatus comprising a thermostatically regulated water bath (p. 4, ln. 4-5) which is an corresponds to the heater claimed by applicant.

18. In Re claim 3, Swanbeck discloses the apparatus comprising thermostatically regulated water bath (p. 4, ln. 4, 5) fully capable to be heated by the radiative heater, and therefore the reference discloses the equivalent of the radiative heater.

19. In Re claim 4, Swanbeck discloses the apparatus comprising the thermostatically regulated water bath (p. 4, ln. 4-5), which is conductively heated component of the apparatus flow path in direct conductive contact with the irrigant and/or wound exudates, and therefore is an equivalent of the conductively heated component

20. In Re claim 5, Swanbeck discloses the apparatus comprising a sterilizing filter 14 (p. 3, ln. 33; Fig. 1) which is an equivalent of a single-phase cleansing system.

21. In Re claim 10, Swanbeck discloses the method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds (p. 2, ln. 32 – p. 4, ln. 12; Fig. 1).

22. In Re claims 11 and 12, Swanbeck discloses the invention discussed above, but does not expressly disclose the apparatus, wherein the means for supplying thermal energy is configured to supply thermal energy to the fluid in the fluid reservoir or in the inlet pipe.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the thermal energy to the fluid in any desired place by relocation the heat conductive element, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (MPEP 2144.04 (VI-C)).

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23. In Re claim 13, Swanbeck discloses the apparatus comprising the outlet tube fully capable of being connected to the waste reservoir.

24. In Re claims 24 and 25, Swanbeck in view of Shettigar disclose the invention discussed above, but do not expressly disclose the particular dislocation of the means for supplying thermal energy to the fluid provided to the wound.

Since Applicant did not state that such particular location of the means for supplying thermal energy serves any specific purpose or performs any specific function other than the function disclosed in Swanbeck, i.e. warming the fluid, such location is the matter of mere rearranging the essential working parts of the invention, and therefore it would have been obvious to those skilled in the art at the time the invention was made to locate the means for supplying the thermal energy being supported by the backing layer and/or surrounding the inlet pipe in order to convenience operation of the device, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (MPEP 2144.04 (VI-C)).

25. In Re claims 14 and 18, Swanbeck discloses the method of treating a wound, comprising the steps of:

providing a conformable wound dressing 10 (Fig. 1) comprising a suction cup that is a cover configured to form a relatively fluid-tight seal around at least a portion of a wound (p. 2, ln. 33);

providing an apparatus comprising:

the feed and discharge tubes (inlet and outlet pipes) A and B (Fig. 1) connected to outlet and discharge tubes 11 and 12 (p. 2, ln. 34, 35; Fig. 1);

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pumping fluid through at least the inlet pipe, the wound dressing, and the outlet pipe (p. 2, ln. 37 – p. 4, ln. 1; Fig. 1);

cleansing the fluid that flows out of the wound dressing (p. 3, ln. 33; Fig. 1);

regulating the fluid that flows out of the wound dressing so that a portion of the fluid that flows out of the wound dressing comprising physiologically active components is recirculated back to the dressing after being cleansed and a portion of the fluid that flows out of the wound dressing is bled through a bleed mechanism and is provided to a waste reservoir; and

heating the fluid before the fluid enters the dressing to maintain the wound at an approximately normothermic range to optimize the metabolic activities of the physiologically active components within the wound dressing and promote wound healing (p. 4, ln. 3-5), wherein the proportion of the amount of fluid provided to the cover and the amount of fluid provided to the cover from the fluid reservoir is necessarily adjusted (claim 18).

Swanbeck does not expressly disclose the portion of the fluid bleeding through a bleed mechanism and provided to a waste reservoir.

Shettigar teaches the blood recovery system comprising valve 62 (Fig. 1) that is a means for leading part of the liquid from the recirculation tube A (Fig. 1) to the external container 48 (Col. 11, lines 34-35; Col. 30, lines 61-62; Fig. 1).

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

26. In Re claim 15, Swanbeck discloses the invention discussed above, but does not expressly disclose the method, wherein the temperature range is between 34 and 40 degrees Celsius.

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The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

27. In Re claim 16, Swanbeck discloses the invention discussed above, but does not expressly disclose the method, wherein the fluid in the fluid reservoir is heated to a temperature approximately within the normothermic range.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to maintain the temperature of the wound treatment fluids between 34 and 40 degrees Celsius, since it was known in the art that the optimal temperature range of the metabolic processes lies within the range of the body temperature that is a normothermic range (See *The Columbia Electronic Encyclopedia*).

28. In Re claim 17, Swanbeck discloses the invention discussed above, but does not expressly disclose the method, wherein the fluid in the fluid reservoir is heated to a temperature slightly above the normothermic range.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to heat the fluid slightly above the normothermic range, since it was known in the art that the fluid loses the temperature while flowing. (**MPEP 2144.03 (A-E)**).

29. In Re claims 26 and 27, Swanbeck in view of Shettigar disclose the invention discussed above, as applied to claim 14, but do not expressly disclose the particular dislocation of the means for supplying thermal energy to the fluid provided to the wound.

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The rationale of obviousness rejection discussed above in claims 24 and 25 is incorporated herein in its entirety.

30. In Re claim 19, Swanbeck discloses a device for rinsing and treating wounds comprising:

a suction cup 10 (Fig. 1) which is the wound dressing made of rubber or plastic (p. 2, ln. 33) that is a backing layer fully capable of forming a fluid-tight seal or closure over a wound; the feed and discharge tubes (inlet and outlet pipes) A and B (Fig. 1) connected to outlet and discharge tubes 11 and 12 (p. 2, ln. 34, 35; Fig. 1); a sterilizing filter (fluid cleansing means) 14 (p. 3, ln. 33; Fig. 1) having an inlet port C (Fig. 1) connected to a fluid offtake tube 12 (Fig. 1) and an outlet port D (Fig. 1) connected to a fluid recirculation tube E (Fig. 1); a fluid reservoir 15 (Fig. 1); a peristaltic pump 13 (p. 2, ln. 37 – p. 4, ln. 1; Fig. 1) which is a device for moving fluid through the wound dressing and cleansing means; an apparatus for supplying thermal energy (p. 4, ln. 3-5).

Swanbeck does not expressly disclose the apparatus comprising a means for bleeding the fluid flow path to bleed fluid from the recirculation tube.

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

31. In Re claim 20, Swanbeck discloses the invention discussed above, but does not expressly disclose the apparatus, wherein the temperature is maintaining between 34 and 40 degrees Celsius.

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

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32. In Re claim 22, In Re claim 3, Swanbeck discloses the apparatus comprising thermostatically regulated water bath (p. 4, ln. 4, 5) fully capable to be heated by the radiative heater, and therefore the reference discloses the equivalent of the radiative heater.

33. In Re claims 28 and 29, Swanbeck in view of Shettigar disclose the invention discussed above, as applied to claim 19, but do not expressly disclose the particular dislocation of the means for supplying thermal energy to the fluid provided to the wound.

The rationale of obviousness rejection discussed above in claims 24 and 25 is incorporated herein in its entirety.

34. Claims 6-8 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Swanbeck (WO 84/01904) in view of Shettigar (US 5,055,198) and further in view of Burbank et al. (WO 00/50143).

35. In Re claim 6, Swanbeck in view of Shettigar disclose the claimed invention discussed above, as applied to claim 1, but do not expressly disclose the apparatus comprising means for fluid cleansing that is a two-phase system, in which the circulating fluid from the wound passes through the means for fluid cleansing and materials deleterious to wound healing are removed, by the circulating fluid coming into direct or indirect contact with another fluid in the means for fluid cleansing.

Burbank teaches the apparatus for peritoneal dialysis which is fully capable of performing cleansing functions for wound healing (See Abstract, ln. 1-7) which is a two-phase system in which the circulating fluid from the wound or body cavity passes through a means for fluid cleansing and materials deleterious to treatment healing are removed by contacting the

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spent fluid with a regeneration solution, which comprises another fluid. Therefore the reference discloses the equivalent of the means for fluid cleansing as claimed.

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of a treatment apparatus that uses a secondary regeneration or treatment solution to clean or regenerate fluid removed from the treatment area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the apparatus of Burbank to the wound treatment device of Swanbeck/ Shettigar in order to provide device with the cleansing apparatus that is known in the art, as demonstrated by Burbank, to be suitable to treat a patient with cleaned recirculated fluid.

36. In Re claims 7 and 8, Swanbeck in view of Shettigar disclose the wound treatment apparatus discussed above, but does not expressly disclose the device comprising the means for fluid cleansing wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable or not selectively permeable to materials deleterious to wound healing.

Burbank teaches the apparatus for peritoneal dialysis which is fully capable of performing cleansing functions for wound healing comprising the means for fluid cleansing wherein the circulating fluid from the wound and the other fluid in the means for fluid cleansing are separated by an integer which is selectively permeable or not selectively permeable to materials deleterious to wound healing (See Abstract, ln. 1-7; P. 18, ln. 4-7).

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The reference discloses the equivalent of the means for fluid cleansing as claimed in claims 7 and 8. The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

Conclusion

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Michele Kidwell/
Primary Examiner, Art Unit 3761